

**REMARKS**

Claims 1-20 are pending and stand rejected. By this response, Applicants amend claims 1-3, 7, 15, and 17-19, and cancel claim 20. Applicants request reconsideration and allowance based on the amendments and remarks submitted herewith.

***Amendments to the Claims***

Applicants amend claims 1, 15, and 19 to clarify that the suture channel is oriented substantially transverse to the longitudinal axis of symmetry of the body. Applicants also amend claims 1 and 15 to recite that the suture anchor is configured to toggle and anchor inside a bone cavity based on tension being applied to a suture in the suture channel, and amend claim 19 to clarify that the step of toggling the suture anchor includes pulling on the attached suture strand such that the flared portion of the anchor penetrates into an inner surface of the bone cavity. Support for this recitation can be found throughout the specification, at least at paragraph [0020] of the published application and in claim 20, which is now cancelled.

Applicants amend claims 2, 3, 17, and 18 to provide the proper antecedent basis, as suggested by the Examiner. Applicants also amend claim 7 to correct a minor typographical error.

No new matter is added. Claims 1-19 are now pending.

***Objections to the Claims***

The Examiner objects to claims 2 and 17, stating that there is insufficient antecedent basis for the limitation “the length.” The Examiner also objects to claims 3 and 18, stating that there is insufficient antecedent basis for the limitation “the width.” As noted above, Applicants amend claims 2, 3, 17, and 18 to correct these informalities, thereby obviating the basis for this rejection.

***Rejections Pursuant to 35 U.S.C. § 102****U.S. Patent No. 6,270,518 of Pedlick*

The Examiner rejects claims 1, 4-13, 15-16, and 19-20 pursuant to 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,270,518 of Pedlick et al. Applicants disagree with the Examiner's rejection.

*Claims 1, 4-13, 15-16, and 19-20*

Independent claims 1 and 15 recite a suture anchor that is configured to toggle and anchor inside a bone cavity based on tension being applied to a suture in the suture channel. In a like manner, independent method claim 19 recites a method of attaching tissue to a bone in a patient's body that includes toggling the suture anchor by pulling on the attached suture strand such that the flared portion of the anchor penetrates into an inner surface of the bone cavity.

Pedlick does not teach or even suggest such a suture anchor or method that relies upon the application of tension to the suture, as required by Applicants' claims. Rather, Pedlick teaches a wedge-shaped suture anchor that is adapted to receive an installation tool for insertion into a bone hole. In use, the user applies a downward pressure to the installation tool to position the anchor within the bone hole. Once positioned, the user *releases* this downward pressure in preparation for withdrawing the device, causing the shaft of the tool to straighten. This straightening force causes one of the edges of the anchor to press into the wall of the bone cavity. As a result, the anchor pivots or rotates within the bone hole such that the anchor securely engages the wall of the one hole. This method is further described in detail at Column 19, lines 33-41 of Pedlick:

Next, the user withdraws installation tool 400 from bore hole 600. As downward pressure on installation tool 400 is released (to be replaced by opposite upward pressure during tool withdrawal), the flexed shaft tip 404 tries to straighten itself, causing the suture anchors sharp, well-defined biting edge 322 to press into wall 602, and causing the suture anchor to pivot slightly in the bore hole so that the suture anchor's cam surface 326 securely engages wall 606 of the bore hole. As the user retracts installation tool 400 from

bore hole 600, rearward movement of installation tool 400 causes progressively more distal portions of the suture anchor's cam surface 326 to come into engagement with wall 606 of the bore hole.

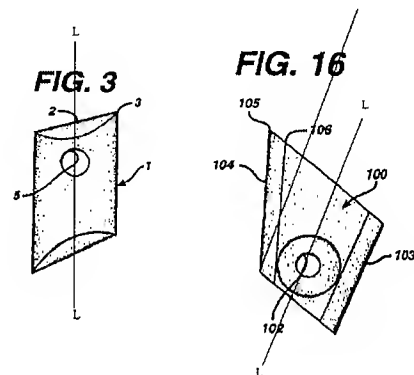
See also, column 9, lines 17-38 (for the embodiment illustrated in FIGS. 9 and 10); column 9, lines 39-62 (for the embodiment illustrated in FIGS. 11 and 12); column 11, lines 40-56 (for the embodiment illustrated in FIGS. 19-25); and column 12, lines 61-65 (for the embodiment illustrated in FIG. 26). In every one of the many embodiments in Pedlick, it is the installation tool that rotates the anchor.

Thus, Pedlick teaches a device and method that are the exact *opposite* of the device and method recited by Applicants' claims. While Applicants' claims require the application of tension to a suture to effect anchoring of the device within bone, Pedlick's device requires the "flexed shaft tip" of an installation tool to pivot the device as it straightens. Pedlick relies on the installation tool to pivot the device, while Applicants' device toggles based on pulling on the suture thread.

Accordingly, because Pedlick does not teach each and every recitation of Applicants' claims, independent claims 1, 15, and 19, as well as claims 4-13 and 16 which depend therefrom, distinguish over Pedlick and represent allowable subject matter.

### Claim 7

In addition to the above, dependent claim 7 further distinguishes over Pedlick. Claim 7 recites that the transverse suture channel is bordered by an opening on each of the two opposed surfaces and that center of the opening is laterally offset with respect to the longitudinal axis of symmetry of the elongate body. These recitations provide specific structure for performing the recited toggling of claim 1. Pedlick, because it is designed to rotate within the bone hole based on flexing of the installation tool, does not have such a channel opening configuration. Rather, Pedlick has a channel where the opposed surfaces are aligned with the longitudinal axis of symmetry of the body, as shown in FIGS. 3 and 16, which are



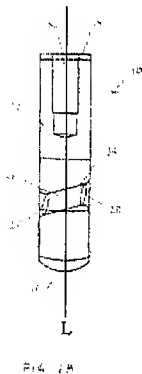
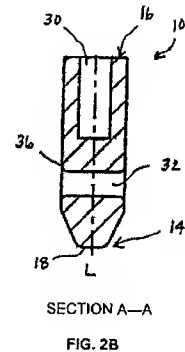
reproduced herein with the longitudinal axis of symmetry L added. Accordingly, dependent claim 7 distinguishes over Pedlick and represents allowable subject matter.

U.S. Patent No. 6,773,436 of Donnelly

The Examiner rejects claims 1, 4-13, 15-16, and 19-20 pursuant to 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,773,436 of Donnelly et al. Applicants disagree with the Examiner's rejection.

Claims 1, 4-13, 15-16, and 19-20

In significant part, independent claims 1, 15, and 19 recite a bone anchor having a suture channel formed in an elongate body for passage of a suture strand therethrough. The suture channel is oriented substantially transverse to a longitudinal axis of symmetry of the body. For example, as shown in FIG. 2B which is reproduced herein, the suture channel 32 extends between the two opposed surfaces and is oriented *transverse* to a longitudinal axis of symmetry L of the body. In use, the device is toggled by applying tension to a suture within the channel to effect engagement with bone.



Donnelly does not teach or even suggest a suture anchor as required by claims 1, 15, and 19. Instead, the bone anchor of Donnelly requires that the suture channel be *obliquely angled* with respect to the longitudinal axis of the body of the anchor. In particular, as shown in FIG. 1B of Donnelly which is also reproduced to the left with reference label L added, the suture channel 24 is *obliquely angled* with respect to the longitudinal axis L of the body. This is completely opposite to the recitations of claims 1, 15, and 19, which require that the suture channel be oriented in a *substantially transverse* direction to the longitudinal axis of the body of the anchor.

Further, Donnelly seeks to provide a bone anchor that can toggle in two planes. As a solution, Donnelly provides an anchor with an obliquely-angled suture channel. In contrast, the claimed invention is concerned with configuring a suture anchor so as to be suitable for reattaching soft tissue to bone in a small joint such as in the hand or skull. Claim 1, 15, and 19 thus provides a suture anchor having a suture channel oriented transversely to the

longitudinal axis of the anchor.

Accordingly, because Donnelly does not teach each and every recitation of Applicants' claims, claims 1, 15, and 19, as well as claims 4-13 and 16 which depend therefrom, distinguish over Donnelly and represent allowable subject matter.

#### Claim 7

In addition to the above, dependent claim 7 further distinguishes over Donnelly. Claim 7 recites that the transverse suture channel is bordered by an opening on each of the two opposed surfaces and that center of the opening is laterally offset with respect to the longitudinal axis of symmetry of the elongate body. These recitations provide specific structure for performing the recited toggling of claim 1. Donnelly, because it is designed to provide toggling in two planes, has an obliquely angled channel, which is centered on the axis of symmetry. To the extent that Donnelly can be said to provide suture channel openings that are located away from the axis of symmetry, the openings are only so placed because Donnelly lacks a transverse suture channel and provides an obliquely angled one. Accordingly, dependent claim 7 distinguishes over Donnelly and represents allowable subject matter.

#### **Rejections Pursuant to 35 U.S.C. § 103**

##### *U.S. Patent No. 6,270,518 of Pedlick*

The Examiner rejects claims 2, 3, 14, 17, and 18 pursuant to 35 U.S.C. § 102(b) as being anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 6,270,518 of Pedlick et al. As noted above, Pedlick does not teach or even suggest the recitations of independent claims 1 and 15. Claims 2, 3, 14, 17, and 18 therefore distinguish over Pedlick at least because they depend from an allowable base claim.

#### Claims 2 and 17

In addition to the above, and as noted by the Examiner in the Office Action, Pedlick does not teach or even suggest a suture anchor with an elongate body having a length in the range of about 2 mm to about 6 mm. Further, and contrary to the assertions of the Examiner, it would not have been obvious for the body of the Pedlick anchor to have a such a length.

Applicants' suture anchors are adapted to reattach tissue to a small bone. In particular, and as stated at paragraph [0028] of the published application:

The suture anchors 10, 110 of the present invention are configured and sized such that they can be used, with sutures, in the repair or reconstruction of collateral ligaments, flexor and extensor tendon at the proximal interphalangeal (PIP), distal interphalangeal (DIP), and metacarpal interphalangeal (MIP) joints of all digits in a patient's hand. Additionally, these anchors 10, 110 can be used to attach soft tissue to the parietal, temporal ridge, frontal, mandible, maxilla, zygoma, and periorbital bones of the skull. Therefore, the suture anchors 10, 110 should have a length sufficient to enable them to properly seat within a small bone such as those mentioned, but be sized and configured to be effective in a surgery to reattach soft tissue to such bone.

As a result, the suture anchors of Applicants' device have an elongate body with a length in the range of about 2 to about 6 mm. The Pedlick anchor is adapted for no such use. Rather, the Pedlick anchor is a conventional suture anchor that can be used for shoulder reconstruction, rotator cuff repair, and hip replacement. All of these procedures take place in the larger bones, and there is no indication that the Pedlick anchor can be used in small bones. Accordingly, one having ordinary skill in the art would have no motivation to give the Pedlick anchor a length in the range of about 2 to about 6 mm as required by Applicants' claims. Claims 2 and 17 therefore further distinguish over Pedlick and represent allowable subject matter.

#### Claim 14

In the Office Action the Examiner rejects claim 14, arguing that it would have been an "obvious design choice to one of ordinary skill in the art at the time the invention was made by the applicant to use blue dye because Applicant has not disclose that the blue dye provides an advantage, or solves a stated problem." Applicants disagree.

As recited in claim 14, Applicants use blue dye facilitate visualization of the suture anchor. Suture anchors are used in bones of all sizes, and generally it does not present challenge for the surgeon to visualize the anchor. However, and as noted above, the anchors of the present invention are used primarily in the small bones, and thus have a smaller size

than the average anchor. Because of the reduced size of the anchors, visualization by a surgeon can be problematic. A visualization tool, such as the blue dye recited by claim 14, is particularly advantageous in that it assists the surgeon in locating the suture anchor within the bone. Visualization is not usually a problem with anchors that are used in larger bones, such as the anchor of Pedlick, and thus a blue dye would be unnecessary for use with the Pedlick anchor. Accordingly, claim 14 further distinguishes over Pedlick and represents allowable subject matter.

U.S. Patent No. 6,77,3436 of Donnelly

The Examiner rejects claims 2, 3, 14, 17, and 18 pursuant to 35 U.S.C. § 102(b) as being anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 6,77,3436 of Donnelly et al. As noted above, Donnelly does not teach or even suggest the recitations of independent claims 1 and 15. Claims 2, 3, 14, 17, and 18 therefore distinguish over Donnelly at least because they depend from an allowable base claim.

Claims 2 and 17

In addition to the above, and as noted by the Examiner in the Office Action, Pedlick does not teach or even suggest a suture anchor with an elongate body having a length in the range of about 2 to about 6 mm. Further, and contrary to the assertions of the Examiner, it would not have been obvious for the body of the Donnelly anchor to have a such a length. Applicants' suture anchors are adapted to reattach tissue to a small bone, as stated in paragraph [0028] of the published application which is reproduced above. As a result, the body of Applicants' suture anchor has a length in the range of about 2 to about 6 mm. The Donnelly anchor is adapted for no such use. While the Donnelly specification states that its anchor is smaller than conventional anchors, this does not mean that the anchor is adapted for use in the small bones. In fact, the Donnelly anchor is not adapted for use in the small bones, and is used in the repair of shoulders. The shoulder is a large bone, and thus there is no motivation for one having ordinary skill in the art to give the Donnelly anchor a length in the range of about 2 to about 6 mm as required by Applicants' claims. Accordingly, claims 2 and 17 further distinguish over Donnelly and represent allowable subject matter.

Claim 14

In the Office Action the Examiner rejects claim 14, arguing that it would have been an “obvious design choice to one of ordinary skill in the art at the time the invention was made by the applicant to use blue dye because Applicant has not disclose that the blue dye provides an advantage, or solves a stated problem.” Applicants disagree.

As recited in claim 14, Applicants use blue dye facilitate visualization of the suture anchor. Suture anchors are used in bones of all sizes, and generally it does not present challenge for the surgeon to visualize the anchor. However, and as noted above, the anchors of the present invention are used primarily in the small bones, and thus have a smaller size than the average anchor. Because of the reduced size of the anchors, visualization by a surgeon can be problematic. A visualization tool, such as the blue dye recited by claim 14, is particularly advantageous in that it assists the surgeon in locating the suture anchor within the bone. Visualization is not usually a problem with anchors that are used in larger bones, such as the anchor of Donnelly, and thus a blue dye would be unnecessary for use with the Donnelly anchor. Accordingly, claim 14 further distinguishes over Donnelly and represents allowable subject matter.

*U.S. Patent No. 5,626,612 of Bartlett*

The Examiner cites U.S. Patent No. 5,626,612 of Bartlett at the end of this rejection and states that Bartlett discloses a “suture anchor having the length of elongate body is in the range of 1-12 mm and the width or largest diameter of the anchor (see entire document).” However, the Examiner does not provide any reasoning why Applicants’ claims are anticipated by or obvious over Bartlett. Thus, Applicants’ claims are allowable over Bartlett.

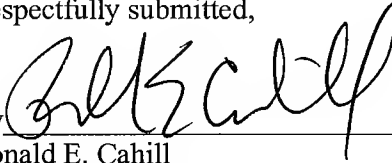


***Conclusion***

Applicants submit that the pending claims are in condition for allowance, and allowance thereof is requested. If the Examiner believes that further communication would expedite the prosecution of this application, Applicants encourage the Examiner to contact the undersigned attorney.

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Respectfully submitted,

By  \_\_\_\_\_

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